

Remarks

Claims 9-23, 25-32, 51, and 52 are pending in the subject application. Applicants have canceled claims 1-8, 24, and 33-50 and, by this Amendment, added new claims 53-60. Support for the new claims can be found throughout the subject specification and in the claims as originally filed (for example, pages 3-11 and pages 22-30). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 9-23, 25-32, and 51-60 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 9-23, 25-32, and 51-52 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The Examiner asserts that claims 9-23, 25-32, and 51-52 are unclear what is the difference between the phrases "mobile sample transport member" and "thermal transport member".

Applicants submit that it is clear from the specification that a "mobile sample transport member" is a mobile element of the microfluidic device on which samples are transported. For example, as recited at page 77, lines 24-27, of the specification as filed:

In another embodiment of the present invention, a device similar to the microfluidics devices described above is used except that the *samples are transported* through the temperature regulated zones on which the thermal transfer members act *using at least one mobile sample transport member rather than microfluidics.* (emphasis added)

Examples of such mobile sample transport members are provided in the specification at page 9, lines 15-24. The sample transport member may consist of, e.g., a film sufficiently hydrophilic to allow adherence of individual liquid sample volumes in the form of droplets, or a filament sufficiently hydrophilic to allow adherence of individual liquid sample volumes in the form of droplets. Applicants further submit that the specification teaches that a "thermal transfer member" is an element of the microfluidic device adapted to heat or cool the sample pathway, as indicated at page 12, lines 25-29:

The thermal transfer member is adapted to heat or cool at least a portion of the at least one sample pathway to at least two temperatures while a sample is continuously flowing along a portion of the sample pathway.

As indicated in the specification, the thermal transfer member may comprise, e.g., a metal bar in fluid communication with a water source containing water at a given temperature (page 4, lines 20-

23), or Peltier elements or any other heating means known in the art (page 80, lines 16-22). Accordingly, Applicants respectfully submit that the difference between the phrases "mobile sample transport member" and "thermal transfer member" is readily apparent, and request that the rejection of claims 9-23, 25-32 and 51-52 under the second paragraph of 35 U.S.C. § 112 be withdrawn.

Claims 9-22, 25-32, and 51 are rejected under 35 U.S.C. § 103(a) as obvious over Bach *et al.* (U.S. Patent No. 6,413,780). Claims 23 and 52 are also rejected under 35 U.S.C. § 103(a) as obvious over Bach *et al.* and further in view of Burns *et al.* (U.S. Patent No. 6,271,021). The Office Action argues that the only difference between the method disclosed in the '780 patent and the claimed invention is either: 1) the use of an atmosphere sufficiently humid to reduce or prevent evaporation of the samples; or 2) the use of mineral oil to prevent evaporation of samples (claims 23 and 52). The Office Action further alleges that reducing or preventing evaporation of samples by carrying out a reaction in a humid atmosphere was common knowledge in the art at the time the invention was filed, and that it would have been *prima facie* obvious to carry out the method disclosed in the '780 patent in an atmosphere sufficiently humid to reduce or prevent evaporation of the samples. The Office Action also alleges that one of ordinary skill in the art would have been motivated to apply the use of mineral oil to reduce or prevent evaporation as taught by U.S. Patent No. 6,271,021 in the method of the '780 patent. These rejections under 35 U.S.C. § 103(a) are respectfully traversed and Applicants respectfully submit that a number of other differences exist between the claimed invention and the methods and apparatus taught by Bach *et al.* (the '780 patent).

It is well-settled law that, to establish the *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 1981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Furthermore, in determining whether a case of *prima facie* obviousness exists, it is necessary to ascertain whether the prior art teachings would appear to be sufficient to one of ordinary skill in the art to suggest making the claimed substitution or other modification (*In re Taborsky*, 502 F.2d 775, 780, 183 U.S.P.Q. 50, 55 (C.C.P.A. 1974)). In the case of the instant invention, it is respectfully submitted that a *prima facie* case of obviousness for the claimed invention has not been established in that the limitations of the claimed invention are not taught by the combination of references.

The '780 patent teaches a method of performing a biochemical reaction in which a mobile sample transport system such as a carousel is used (see Figure 3A). This mobile sample transport system comprises containers 1. Containers 1 are moved through a process path 11 to various locations along the process path 11 (see column 7, lines 48 to 56). The process path 11 may be kept at one temperature or any desired number of temperatures (see column 7, lines 62 to 24, emphasis added). In one embodiment, one portion of the process path 11 may be maintained at about 37°C while another portion of the process path 11 may be maintained at about 70°C (see column 7, lines 66-67, to column 8, lines 1-2; emphasis added). Thus, the '780 patent teaches a method that utilizes a number of temperature regulated zones that are thermostated to be maintained at a single temperature.

Applicants further point out that in the '780 patent, the different portions of the process path 11 are preferably thermally insulated to guarantee a standardized temperature in each portion the process path (see column 8, lines 15-22). In contrast, a device for performing the method of present invention can subject samples to different thermal temperatures in a single temperature regulated zone, and hence has no requirement for thermal insulation. Accordingly, the method of the present invention is advantageous over prior art since a device for performing the method of present invention requires less space and allows for miniaturization.

In contrast, claim 9 of the present invention is directed to a method of performing a biochemical reaction wherein the mobile sample transport member moves along a pathway such that sample receiving regions move through at least one temperature regulated zone upon which a thermal transfer member acts, wherein *said thermal transport member cycles between at least two temperatures while said sample receiving regions are moving through said at least one temperature regulated zone* (see claim 9, lines 4-7, emphasis added). Thus, the method of the instantly claimed invention does not use temperature regulated zones that are thermostated to a single temperature; rather, the claimed methods provide that the sample is in at least one temperature regulated zone that cycles between at least two different temperatures (see, for example, claim 9 and claims 25-26). Accordingly, since the process path of the '780 patent comprises one or several portions kept at a given temperature, whereas the pathway of the present invention comprises one or more portions cycling between at least two temperatures, the method disclosed in the '780 patent does not teach,

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suggest, or render obvious the present invention and it is further submitted that the addition of the teachings of Burns *et al.* (U.S. Patent No. 6,271,021) fail to remedy the defects in the teachings of Bach *et al.* as the reference is used for the teaching of covering sample receiving regions with mineral oil to prevent evaporation.

Applicants further submit that the Office Action fails to address a number of additional limitations of the dependent claims. For example, the Office Action fails to address the limitations of claims 13, 14, 15, 16, 17, 19, 20, 21, 22, 23, 25, 26, 27, 29, or newly presented claims 53-60. In view of the above, Applicants respectfully submit that the differences between the method disclosed in the '780 patent and the claimed invention is not limited to the use of a humid atmosphere or to the use of mineral oil. Accordingly, it is respectfully submitted that the methods of claims 9, 23, 51 and 52 are not unpatentable over the '780 patent, alone, or in combination with the '021 patent. Since claims 10-22 and 25-32 depend directly or indirectly of claim 9, Applicants respectfully request withdrawal of rejection of claim 9-23, 25-32, and 51-52 under 35 U.S.C. § 103(a).

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

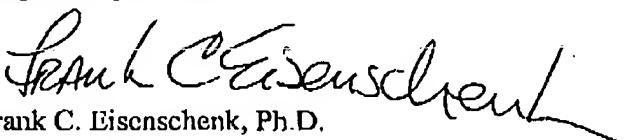
The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

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Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,


Frank C. Eischenschenk, Ph.D.
Patent Attorney
Registration No. 45,332
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

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SALIWANCHIK, LLOYD & SALIWANCHIK
A Professional Association
2421 N.W. 41st Street
Suite A-1
Gainesville, FL 32606

OFFICIAL

Telephone (352) 375-8100
Facsimile (352) 372-5800

TO: Examiner Joyce Tung

FROM: Frank C. Eischenschenk, Ph.D.

COMPANY: U.S. Patent Office, Art Unit 1637

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SUBJECT/MESSAGE:

U.S. Patent Application Docket No. G-069US02CIP
(Fouillet et al.)
METHOD FOR CARRYING OUT A BIOCHEMICAL PROTOCOL IN
CONTINUOUS FLOW IN A MICROREACTOR
Serial No. 09/772,280; filed January 29, 2001

Attachments: Petition and Fee for Extension of Time Under 37 CFR §1.136(a) (1 page)
Amendment Under 37 C.F.R. § 1.111 (11 pages)

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